Initial Approval Date: July 10, 2019
Revised Dates: October 9, 2019

CRITERIA FOR PRIOR AUTHORIZATION

Ulcerative Colitis Agents

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in table 1 below.

Adalimumab (Humira®, Amjevita™, Cyltezo™, Hyrimoz™, Hadlima™)
Golimumab (Simponi®)
Infliximab (Remicade®, Reflexis™, Inflectra®, Ixifi™)
Tofacitinib (Xeljanz®)
Vedolizumab (Entyvio®)

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- Must be prescribed by or in consultation with a gastroenterologist.
- ~~Patient must have had an adequate trial (at least 90 consecutive days within the past 120 days) of or contraindication to induction of remission using a corticosteroid, and subsequent maintenance with a thiopurine listed in Table 2.[4,5,6,7,8,9,10,11,12]~~
- Patient must meet ONE of the following for induction of remission as determined by the provider:
  - Had an adequate trial (at least 4 weeks)[2] of an oral systemic corticosteroid equivalent to 40-60 mg/day prednisone with a planned dose taper.[1]
  - Had an inadequate response within 3-5 days of an intravenous corticosteroid (IVCS) equivalent to 60 mg/day methylprednisolone or 100 mg hydrocortisone 3-4 times per day for the induction of remission.[1]
- Patient must fail to achieve mucosal healing within 4 months[3] or have had a relapse at any time despite continuous use of any conventional therapy listed in Table 2 for the maintenance of remission. Mucosal healing is defined as ONE of the following:[1,~~3~~]
  - Endoscopic evidence of mucosal healing defined as Mayo subscore ≤ 1.[1]
  - Fecal Calprotectin ≤ 150 µg/g.[1]
- For all agents listed, the preferred PDL drug, if applicable, which covers this indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Prescriber must provide baseline of at least ONE of the following assessments of moderate to severe disease:[1]
  - ~~C-reactive protein (CRP) is elevated~~
  - Fecal calprotectin (FC) > 150 µg/g[1]
  - Endoscopy Mayo subscore ≥ 2[1]
- For all requested immunomodulating biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another immunomodulating biologic or JAK inhibitor listed in Table ~~2~~3. After discontinuing the current immunomodulating biologic or JAK inhibitor, the soonest that a new immunomodulating biologic or JAK inhibitor will be authorized is at the next scheduled dose.

Table 1. FDA-approved age and dosing limits of Ulcerative Colitis (UC) Agents.[4-14]

Medication	Indication(s)	Age	Dosing Limits
Janus Associated Kinase Inhibitors			
Tofacitinib (Xeljanz®)	UC	≥ 18 years	Immediate release: 10 mg orally twice daily for 8 weeks then 5 or 10 mg twice daily
Selective Adhesion-Molecule Inhibitor			
Vedolizumab (Entyvio®)	UC	≥ 18 years	300 mg IV at 0, 2, and 6 weeks, and then every 8 weeks thereafter.
Tumor Necrosis Factor-Alpha (TNF-α) Blockers			
Adalimumab (Humira®, Amjevita™, Cyltezo™, Hyrimoz™, Hadlima™)	UC	≥ 18 years	160 mg initially SC on day 1 (given on day 1 or split and given over 2 consecutive days), followed by 80 mg 2 weeks later (day 15) and then 40 mg every other week beginning 2 weeks later (day 29).
Golimumab (Simponi®)	UC	≥ 18 years	200 mg initially SC at week 0, followed by 100 mg at week 2 and then 100 mg every 4 weeks.
Infliximab (Remicade®, Renflexis™, Inflectra®)	UC	≥ 6 years	5 mg/kg at IV 0, 2, and 6 weeks, then every 8 weeks.
Infliximab (~~Renflexis™, Inflectra®,~~ Ixifi™)	UC	≥ 18 years	5 mg/kg at IV 0, 2, and 6 weeks, then every 8 weeks.

SC: subcutaneous. IV: intravenous

LENGTH OF APPROVAL (INITIAL): 12 months

CRITERIA FOR RENEWAL PRIOR AUTHORIZATION: (must meet all of the following)

- Prescriber must provide at least ONE of the following response measure(s):
  - Endoscopic evidence of mucosal healing defined as ONE of the following:
    - Mayo subscore ≤ 1.[1]
  - ~~Normalization of CRP.[1]~~
    - Fecal Calprotectin ≤ ~~200~~150 µg/g.[1]
- Must not exceed dosing limits listed in Table 1.
- For all requested immunomodulating biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another immunomodulating biologic or JAK inhibitor listed in Table ~~2~~3. After discontinuing the current immunomodulating biologic or JAK inhibitor, the soonest that a new immunomodulating biologic or JAK inhibitor will be authorized is at the next scheduled dose.

LENGTH OF APPROVAL (RENEWAL): 12 months

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

Table 2. List of conventional therapy in the treatment of UC[1,3]

Conventional Agents for Maintenance of Remission of Moderate to Severe UC	
Generic Name	**Brand Name**
Azathioprine	Azasan®, Imuran®
Mercaptopurine	Purinethol®

Table ~~23~~. List of immunomodulating biologic agents/janus kinase inhibitors (agents not to be used concurrently)

Biologic Agents/Janus Kinase Inhibitors		
Actemra® (tocilizumab)	Hyrimoz™ (adalimumab-adaz)	Ruxience™ (rituximab-pvvr)
Amevive® (alefacept)	Ilaris® (canakinumab)	Siliq® (brodalumab)
Amjevita™ (adalimumab-atto)	Ilumya™ (tildrakizumab-asmn)	Simponi® (golimumab)
Cimzia® (certolizumab)	Inflectra® (infliximab-dyyb)	Simponi Aria (golimumab)
Cinqair® (reslizumab)	Ixifi™ (infliximab-qbtx)	Skyrizi™ (Risankizumab)
Cosentyx® (secukinumab)	Kevzara® (sarilumab)	Stelara® (ustekinumab)
Cyltezo™ (adalimumab-adbm)	Kineret® (anakinra)	Taltz® (ixekizumab)
Dupixent® (benralizumab)	Nucala® (mepolizumab)	Tremfya® (guselkumab)
Enbrel® (etanercept)	Olumiant® (baricitinib)	Truxima® (rituximab-abbs)
Entyvio® (vedolizumab)	Orencia® (abatacept)	Tysabri® (natalizumab)
Erelzi™ (etanercept-szzs)	Remicade® (infliximab)	Xeljanz® (tofacitinib)
Eticovo® (etanercept-ykro)	Renflexis® (infliximab-abda)	Xeljanz XR® (tofacitinib)
Fasenra™ (benralizumab)	Rinvoq™ (upadacitinib)	Xolair® (omalizumab)
Hadlima™ (adalimumab-bwwd)	Rituxan® (rituximab)	
Humira® (adalimumab)	Rituxan Hycela™ (rituximab/hyaluronidase)	

Table 4. Relative Potencies for Oral/Intravenous Corticosteroids.[15]

Glucocorticoid	Relative Potency
Short-Acting	
Cortisone	25
Hydrocortisone	20
Intermediate-Acting	
Prednisone	5
Prednisolone	5
Methylprednisolone	4
Long-Acting	
Dexamethasone	0.75

Table 4 is intended for reference only.

Notes:

Adalimumab	Only continue adalimumab in patients who have shown evidence of clinical remission by eight weeks (Day 57) of therapy.
Golimumab	Simponi Aria is not indicated for ulcerative colitis (UC).
Tofacitinib	Use of tofacitinib in combination with biological therapies for UC or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended. Discontinue tofacitinib after 16 weeks of 10 mg twice daily, if adequate therapeutic benefit is not achieved. Xeljanz XR is not indicated for ulcerative colitis (UC).

Vedolizumab	Discontinue vedolizumab in patients who show no evidence of therapeutic benefit by week 14.

References:

1. ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol 2019; 114:384-413. Available at https://journals.lww.com/ajg/Pages/ACG-Clinical-Guidelines.aspx. Accessed on 6/24/19.
2. Glucocorticosteroid Therapy in Inflammatory Bowel Disease: Systematic Review and Meta-Analysis. Am J of Gastroenterol 2011; 106(4): 590-9. Available at https://insights.ovid.com/pubmed?pmid=21407179. Accessed on 7/16/19.
~~2.~~3. Efficacy of Immunosuppressive Therapy for Inflammatory Bowel Disease: A Systematic Review and Meta-Analysis. Am J Gastroenterol 2011; 106(4): 630-42. Available at https://insights.ovid.com/pubmed?pmid=21407186. Accessed on 7/16/19.
~~3.~~4. Humira (adalimumab) [prescribing information]. North Chicago, IL: AbbVie Inc; December 2018.
~~4.~~5. Amjevita (adalimumab-atto) [prescribing information]. Thousand Oaks, CA: Amgen Inc; March 2018.
~~5.~~6. Cyltezo (adalimumab- adbm) [prescribing information]. Ridgefield, CT; Boehringer Ingelheim Pharmaceuticals Inc: August 2017.
~~6.~~7. Simponi (golimumab) [prescribing information]. Horsham, PA: Janssen Biotech Inc; March 2018.
~~7.~~8. Remicade (infliximab) [prescribing information]. Horsham, PA: Janssen Biotech Inc; June 2018.
~~8.~~9. Inflectra (infliximab-dyyb) [prescribing information]. New York, NY: Pfizer; ~~September 2018~~June 2019.
~~9.~~10. Renflexis (infliximab-abda) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; ~~March~~ June 2019.
~~10.~~11. Ixifi (infliximab-qbtx) [prescribing information]. Ringaskiddy, Co. Cork, Ireland: Pfizer Ireland Pharmaceuticals; December 2017.
~~11.~~12. Xeljanz/Xeljanz XR (tofacitinib) [prescribing information]. New York, NY: Pfizer; October 2018.
~~12.~~13. Entyvio (vedolizumab) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America Inc; May 2019.
14. Hadlima (adalimumab-bwwd) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; July 2019.
15. Solu-Medrol (methylprednisolone sodium succinate) [prescribing information]. New York, NY: Pfizer; July 2018.

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR

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DATE

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PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

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DATE